

Aptima® Assay Fluids Kit (Panther® System)

Instructions for Use
For *in vitro* diagnostic use

Intended Use

The Aptima® Assay Fluids Kit is an ancillary required to perform the Aptima assays on the Panther/Panther Fusion® System and for specimen processing. The Aptima Assay Fluids Kit consists of the following components:

- Aptima Wash Solution — HEPES buffered solution containing <2% detergent used to wash the samples prior to the addition of the amplification reagents.
- Aptima Buffer for Deactivation Fluid — Bicarbonate buffer solution that is added to bleach. The buffered bleach is added to amplification reactions to destroy amplicon.
- Aptima Oil Reagent — Silicone oil, used as an overlay to serve as a non-aqueous barrier to reduce the amount of evaporation that could occur during the various incubations required during the test. This overlay also serves as a barrier to reduce the chance of carry-over contamination within the laboratory environment.

Materials Provided

Aptima Assay Fluids Kit (Cat No. 303014)

(Store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity
W	Aptima Wash Solution <i>10 mM HEPES buffered solution containing less than 2% preservative.</i>	1 x 2.9 L
O	Aptima Oil Reagent <i>Silicone oil.</i>	1 x 260 mL
DF	Aptima Buffer for Deactivation Fluid <i>800 mM Bicarbonate buffered solution.</i>	1 x 1.4 L

Warnings and Precautions

- A. Use routine laboratory precautions.
- B. For professional use.
- C. Avoid microbial and ribonuclease contamination of Aptima Assay Fluids.

Storage and Handling Requirements

- A. Store unopened Aptima Assay Fluids at 15°C to 30°C.
- B. Once opened, Aptima Assay Fluids are stable for 60 days.
- C. Do not use after the expiration date.
- D. Some reagents of this kit are labeled with risk and safety symbols.

Note: Hazard communication information for labeling of globally marketed products reflects the US and EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicds.com.

US Hazard Information	
	<p>Buffer For Deactivation Fluid SODIUM HYDROXIDE 1 – 5% SODIUM HYPOCHLORITE <1%</p> <p>WARNING H315 – Causes skin irritation H319 – Causes serious eye irritation P264 – Wash face, hands and any exposed skin thoroughly after handling P280 – Wear protective gloves/protective clothing/eye protection/face protection P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337 + P313 – If eye irritation persists: Get medical advice/attention P302 + P352 – IF ON SKIN: Wash with plenty of soap and water P332 + P313 – If skin irritation occurs: Get medical advice/attention P362 – Take off contaminated clothing and wash before reuse H411 - Toxic to aquatic life with long lasting effects H401 - Toxic to aquatic life</p>
	<p>Aptima Oil POLYDIMETHYLSILOXANE 95 – 100%</p> <p>WARNING H315 – Causes skin irritation H319 – Causes serious eye irritation P264 – Wash face, hands and any exposed skin thoroughly after handling P280 – Wear protective gloves/protective clothing/eye protection/face protection P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337 + P313 – If eye irritation persists: Get medical advice/attention P302 + P352 – IF ON SKIN: Wash with plenty of soap and water P332 + P313 – If skin irritation occurs: Get medical advice/attention P362 – Take off contaminated clothing and wash before reuse</p>
EU Hazard Information	
 	<p>Buffer For Deactivation Fluid SODIUM HYDROXIDE 1 – 5% SODIUM HYPOCHLORITE < 1%</p> <p>WARNING H315 – Causes skin irritation H319 – Causes serious eye irritation H411 – Toxic to aquatic life with long lasting effects P273 – Avoid release to the environment P280 – Wear eye protection/face protection</p>
	<p>Aptima Oil POLYDIMETHYLSILOXANE 100%</p> <p>WARNING H315 – Causes skin irritation H319 – Causes serious eye irritation</p>

Procedure

Replace bottles in the Universal Fluids Drawer when notified by the system. Refer to the *Panther System Operator's Manual*.

Contact Information and Revision History



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For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.

This product is intended for use only in the field of human in vitro diagnostics.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

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This product may be covered by one or more U.S. patents identified at www.hologic.com/patents.

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AW-26509-001 Rev.002
2022-05

Revision History	Date	Description
AW-26509-001 Rev. 001	May 2022	<ul style="list-style-type: none"> Created Aptima Assay Fluids Kit IFU AW-26509-001 Rev. 001 based on 502181EN Rev. 005 for regulatory compliance with IVDR Added Instructions for Use Updated the Intended Use section Added Global GHS notification Updated the Buffer for Deactivation Fluid, US Hazardous information and EU Hazardous information to reflect the Safety Data Sheet Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support
AW-26509-001 Rev. 002	May 2022	<ul style="list-style-type: none"> Editorial change - no change to content